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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MEYER GLICKSTEIN, Plaintiff, v. ROCHE DIAGNOSTICS CORP., PATIENT HOME MONITORING, INC., and JOHN DOE CORPORATIONS 1 THROUGH 50. Defendants.	No. 1:16-cv-01678-RBK-KMW AMENDED COMPLAINT JURY TRIAL DEMANDED

Plaintiff, Meyer Glickstein, by his designated attorneys, for his Amended Complaint, alleges as follows based upon personal knowledge, the investigation of counsel, information and belief, and publically available information:

NATURE OF THE ACTION

1. This is a products liability action arising from a defective medical device and supplies manufactured and/or distributed by Defendant Roche Diagnostics ("Roche") and Defendant Patient Home Monitoring, Inc. ("PHM").

2. Plaintiff used these products upon a prescription from his doctor and in accordance with their instructions and intended uses and, as a result of their defects, Plaintiff suffered serious injuries as described below.

PARTIES

3. Plaintiff, Meyer Glickstein, is a natural person and citizen of New Jersey. Plaintiff brings this action for injuries suffered as a proximate result of Plaintiff being prescribed and using the defective medical products CoaguChek XS Meter ("Meter") and CoaguChek XS PT Test Strips ("Test Strips").

4. Defendant Roche is a medical device manufacturer and/or distributor. Roche is incorporated in the State of Indiana and has its North American headquarters at 9115 North Hague Rd., Indianapolis, Indiana.

5. Defendant PHM is a medical device supplier incorporated in the State of Washington, and it has its principal place of business at 14724 Ventura Blvd Ste. 1250., Sherman Oaks, California.

6. Defendants, John Doe Corporations 1 through 50, are fictitious names for the as-yet-unidentified business entities who are liable, or partly liable, to the Plaintiff herein, as discovery may reveal. Plaintiff reserves the right to amend this complaint to substitute the actual identities of liable entities in place of the fictitiously named parties, with all such amendments relating back to the original date of filing.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 USC § 1332 because Plaintiff and Defendants are citizens of different states and the amount in controversy exceeds $75,000, exclusive of interests and costs.

8. This Court has personal jurisdiction over Defendants because Defendants have sufficient minimum contacts with New Jersey such that the exercise of jurisdiction by this Court is consistent with notions of fair play and substantial justice: Defendants conduct business in New Jersey, distribute and sell the Meter and Test Strips in New Jersey, and produce and disseminate advertisements and marketing materials that are reasonably calculated to reach New Jersey residents. Moreover, this action arises out of or relates to these contacts.

9. Venue is proper in this District pursuant to 28 USC § 1391 because Defendants are subject to personal jurisdiction in this Court in this action. Moreover, a substantial part of the events giving rise to this action occurred in this District.

FACTUAL ALLEGATIONS

10. The Meter is a medical device that measures the International Normalized Ratio ("INR") of blood. INR is a calculation made to standardize prothrombin time ("PT"), which is a measure of how long it takes blood to clot.

11. Defendants advertised and marketed – and continue to advertise and market – the Meter and Test Strips to both medical professionals and consumers through a variety of literature and media, including websites with printed marketing materials and embedded videos.[1]

12. The Meter and Test Strips are designed for home use by individuals taking anticoagulants such as warfarin. Anticoagulants inhibit the blood clotting process, which in turn helps prevent blood clots from forming and causing blockages, such as a heart attack or stroke.

[1] *See The CoaguChek® XS system*, Roche, http://coaguchekmyinr.com/choosing-a-meter/the-coaguchek-xs-system (last accessed April 13, 2016); *Products and Solutions*, Roche, http://coaguchek-usa.com/products-and-solutions (last accessed April 13, 2016).

13. Users test their INRs by using a lancet to draw blood from one of their fingers, placing a drop of blood on a Test Strip, and inserting the Test Strip into the Meter. The Meter measures the PT of the blood, calculates the INR, and displays the INR to the user.

14. It is critical that individuals undergoing anticoagulant therapy frequently test their INR, and it is equally critical that the INR results are accurate. Anticoagulants such as warfarin have a narrow therapeutic range; the response to a standard dose varies widely between patients and within a patient over time. If the dose is too high or too low, the patient is at risk of serious injury or death from, *inter alia*, a stroke, heart attack, or internal hemorrhaging. Accordingly, INR must be frequently and accurately measured so healthcare providers can make dosage adjustments to ensure maximum safety and efficacy of the anticoagulants.

15. The Meter and Test Strips were defective and provided inaccurate INR results in many patients, thereby placing users at extreme risk of receiving dangerously incorrect doses of anticoagulants.

16. Defendants have known about the defects for several years, as the Meter and Test Strips, and similar units and strips manufactured and/or distributed by Defendants, have been recalled numerous times, and at least five recalls have been for inaccurate or erroneous test results.[2]

17. The Meter and Test Strips caused Plaintiff to suffer a stroke as a result of their inaccurate readings of his INR.

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[2] *See Medical Device Recalls*, FDA, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=&productdescriptiontxt=coaguchek&productcode=&IVDProducts=&rootCauseText=&recallstatus=&centerclassificationtypetext=&recallnumber=&postdatefrom=&postdateto=&productshortreasontxt=&firmlegalnam=&PMA_510K_Num=&pnumber=&knumber=&pagenum=10&sortcolumn=cdd (last accessed April 14, 2016).

18. In 2011, Plaintiff was diagnosed with atrial fibrillation and was prescribed warfarin.

19. Starting in 2011, Plaintiff regularly had his INR tested by AtlantiCare Clinical Laboratories in Ventnor, New Jersey. AtlantiCare sent the results to Plaintiff's cardiologist, Dr. Howard Weitz, at Jefferson University Hospital in Philadelphia, Pennsylvania, who then adjusted Plaintiff's warfarin dose as necessary.

20. In or around March 2014, Plaintiff was prescribed, and started using, a Meter and Test Strips.

21. The Meter and Test Strips were manufactured and/or distributed by Defendant Roche.

22. Defendant PHM supplied Plaintiff with the Meter and Test Strips.

23. Plaintiff used the Meter and Test Strips in accordance with their intended use and the instructions given to him by his doctors, Defendant Roche, and/or Defendant PHM.

24. Each time Plaintiff tested his blood, he reported the results to Defendant PHM, which in turn reported them to Plaintiff's healthcare providers at Jefferson Hospital.

25. On or around March 30, 2014, Plaintiff went to the emergency room for dizziness and lightheadedness.

26. On April 14, 2014, Plaintiff suffered a stroke.

27. Plaintiff's lightheadedness, dizziness, and stroke occurred because a defect in the Meter and/or Test Strips caused the Meter to return significantly inaccurate INR results, which in turn prevented Plaintiff's healthcare providers from prescribing a safe and effective dose of warfarin in a timely manner.

COUNT I
DEFECTIVE DESIGN – PRODUCTS LIABILITY
(On behalf of Plaintiff against all Defendants)

28. The foregoing paragraphs of this Amended Complaint are realleged and incorporated by reference.

29. At all times relevant to this action, all Defendants designed, researched, developed, manufactured, tested, labeled, marketed, sold, and/or distributed the Meter and Test Strips, which were prescribed for and used by Plaintiff.

30. The Meter and Test Strips were expected to, and did, reach Plaintiff without substantial change in their conditions.

31. Plaintiff used the Meter and Test Strips in accordance with their intended use and the instructions given to Plaintiff by his doctors, Defendant Roche, and/or Defendant PHM.

32. At all times relevant to this action, the Meter and Test Strips were not reasonably fit, suitable, or safe for their intended purposes because they were designed in a defective manner. Namely, they provided substantially inaccurate INR results.

33. At the time the Meter and Test Strips left the control of Defendants, there existed safer alternative PT/INR testing devices.

34. Accordingly, a practical and technically feasible alternative design existed that would have enabled the Meter and Test Strips to accurately measure INR levels without substantially impairing the reasonably anticipated or intended function of the Meter and Test Strips.

35. When the Meter and Test Strips left the hands of Defendants, their defects rendered them unreasonably dangerous and more dangerous than an ordinary consumer would expect.

36. The characteristics of the Meter and Test Strips are not known to the ordinary consumer, their defects are not inherent characteristics of PT/INR monitoring kits, and the defects would not be recognized by the ordinary person to whom the devices were prescribed.

37. The defects are not unavoidably unsafe aspects of the Meter and Test Strips, and Defendants did not provide adequate warnings or instructions, as alleged *infra*.

38. As a direct and proximate result of Plaintiff's use of the Meter and Test Strips, Plaintiff developed serious health problems and suffered damages including, without limitation, past, present and future pain and suffering, serious physical injuries, loss of enjoyment of life, and past and future medical expenses.

WHEREFORE, Plaintiff demands judgment against the Defendants for any and all damages including, without limitation, damages for physical and emotional pain and suffering, loss of enjoyment of life, and past and future medical expenses, together with interest, costs, and attorney's fees as allowed by law, and any and all such other relief as the Court deems just and proper.

COUNT II
FAILURE TO WARN – PRODUCTS LIABILITY
(On behalf of Plaintiff against all Defendants)

39. The foregoing paragraphs of this Amended Complaint are realleged and incorporated by reference.

40. At all times relevant to this action, Defendants designed, researched, developed, manufactured, tested, labeled, marketed, sold, and/or distributed the Meter and Test Strips, and in the course of the same directly advertised and marketed the Meter and Test Strips to consumers, and therefore had a duty to warn of the risks of harm associated with using the Meter and Test Strips.

41. The Meter and Test Strips were expected to, and did, reach Plaintiff without substantial change in their conditions. Moreover, the failure to warn existed before the devices left the Defendants' control.

42. Plaintiff used the Meter and Test Strips in accordance with their intended use and the instructions given to Plaintiff by his doctors and/or Defendants.

43. Defendants failed to provide adequate and proper warnings and labeling that accurately and fully informed health care providers and consumers of the existence, nature, scope, degree, and incidence of clinically significantly erroneous INR results being returned by the Meter and Test Strips. Indeed, Defendants failed to warn health care professionals and consumers that the Meter and/or Test Strips contain a defect that can cause them to return significantly inaccurate results.

44. Indeed, Defendants knew of the serious and life-threatening risks associated with the use of the Meter and Test Strips, and they failed to disclose these risks.

45. If Defendants had properly and adequately warned about these risks, Plaintiff's doctor would not have prescribed the Meter or Test Strips.

46. If Defendants had properly and adequately warned about these risks, Plaintiff would not have used the Meter or Test Strips.

47. As a direct and proximate result of Defendants failure to warn, Plaintiff developed serious health problems and suffered damages including, without limitation, past, present and future pain and suffering, serious physical injuries, loss of enjoyment of life, and past and future medical expenses.

WHEREFORE, Plaintiff demands judgment against the Defendants for any and all damages including, without limitation, damages for physical and emotional pain and suffering,

loss of enjoyment of life, and past and future medical expenses, together with interest, costs, and attorney's fees as allowed by law, and any and all such other relief as the Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff seeks judgment against all Defendants, and each of them, individually, and jointly and severally. Plaintiff requests the following relief, as appropriate, as to each and every count alleged in this Amended Complaint:

a. Compensatory damages for past and future injuries, including, but not limited to, the physical, emotional, and mental pain and suffering endured by Plaintiff;

b. All past, present, and future related medical and healthcare costs incurred by Plaintiff;

c. Prejudgment and post-judgment interest;

d. Costs of suit;

e. Attorneys' fees, as allowed by law;

f. Such other relief as the Court deems just and proper.

Dated: April 14, 2016

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff demands a trial by jury for all issues so triable.

Dated: April 14, 2016

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